K110960

JUL 14 2011

Royal Imperial Nitrile Examination Gloves
Textured Powder-Free Blue 510(k) Summary

Date prepared: June 3, 2011

Name and Address of Sponsor

Koon Seng SDN. BHD.
16058, Kaw. Perindustrian Tangkak,
84900 Tangkak, Johor, Malaysia
Ph: 606-979 1778
Fax: 606-979 1779
Email: koonsen@po.jaring.my

Name and Address of Official Correspondent

Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121
Contact: Mr. Kevin Walls, RAC
Tel: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

Device Name

Trade Name: Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue
Common Name: Patient examination glove
Classification Name: Polymer patient examination glove

Classification, Panel and Product Code

Class 1, General Hospital, LZA

Substantial Equivalence

The Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue are substantially equivalent to the Ultrawin SDN BHD Non-Sterile, Powder Free Nitrile Examination Gloves (K090828).

Device Description

The Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue is a class I medical device classified under Product Code LZA. It is a single-use disposable device that meets all requirements of ASTM D 6319-10.

K110960

Indications for Use

The Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue is a single-use disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Intended Use

The Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue is intended to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Non-clinical Testing Data

The Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue was tested in accordance, and found to be in compliance, with ASTM D3578-05, ASTM D6124-06, ASTM D6319-10 and ISO 10993-10. The test reports and the Forms FDA 3654 may be found in the body of the 510(k) premarket notification.

Conclusion Statement

Based on the fact that the Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue passed all the tests associated with the FDA-recognized consensus standards listed above, the Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Koon Seng SDN. BHD.
C/O Mr. Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Incorporated
5401 South Cottonwood Court
Greenwood Village, Colorado 80121

JUL 14 2011

Re: K110960
Trade/Device Name: Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 3, 2011
Received: June 7, 2011

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110960

Device Name: Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue

Indications for Use: The Royal Imperial Nitrile Examination Gloves Textured Powder-Free Blue is a single-use disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110960